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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,139	11/20/2001	Mark Thiede	640100-420	9767

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,139

Applicant(s)

THIEDE ET AL.

Examiner

Joseph T. Voitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 9-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 national stage filing of PCT/US99/26927, filed November 12, 1999, which claims benefit to provisional application 60/108,357, filed November 13, 1998.

Claims 1-27 are pending.

Election/Restriction

Applicant's election of group II, claims 6-8, with traverse is acknowledged. It was noted that because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-27 are pending. Claims 1-5, 9-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 6-8 are currently under examination drawn to a method of engrafting mesenchymal stem cells comprising administering mesenchymal stem cells *in utero*.

This application contains claims drawn to nonelected invention elected with traverse (see paper 3, page 1). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1632

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 101

Claims 6-8 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a well asserted utility or a well established utility.

Applicants summarize the nature of the invention encompassed by the claims (top of page 2). Applicants summarize each of the working examples provided in the instant specification noting that implanted mesenchymal stem cells were transplanted *in utero* and were able to implant and proliferate into several cell types in the resulting animal (pages 2-4). Applicants argue that “the results shown in the specification provide the basis for employing prenatal mesenchymal stem cell transplantation in order to provide a reservoir of normal stem cells to replace defective cells as they become damaged in degenerative diseases with progressive cellular and organ damage” (page 4 of Applicants’ amendment and page 25 of the specification). Applicants argue that this is a specific and substantial utility, and that every utility need not be demonstrated nor operable citing *Ex parte Mark* (page 5). Applicants argue that in light of the working examples the office has failed to demonstrate that the claimed method has no utility. See Applicants’ amendment, pages 2-5. Applicants arguments have been fully considered, but not found persuasive.

Initially, it is noted that each of the proposed utilities taught in the specification were specifically discussed in the previous office action in the basis of the rejection. Applicants have focused on only one of the cited utilities that is MSC transplantation may provide a "reservoir" of

Art Unit: 1632

normal stem cells to replace defective cells as they become damaged in degenerative diseases with progressive cellular and organ damage (page 25), and have not provided any discussion for the use in (1) large scale tissue engineering particularly for repair of musculoskeletal injury; 2) cellular therapy for diseases of mesenchymal origin such as muscular dystrophy, osteoporosis, osteogenesis imperfecta, and collagen disorders; 3) bone marrow conditioning to facilitate engraftment of autologous or allogeneic hematopoietic stem cells; and 4) gene therapy; each of which are in part representative of the ability of the implanted cells to act in a tissue or organ to affect the desired treatment (previous office action page 3 and page 25 of the specification).

Moreover, it is noted that the Examiner acknowledged the working examples in the specification but indicated that the basis of the rejection focuses on the fact that while the specification reduces to practice the *in utero* transplantation of mesenchymal stem cells, the specification fails to provide a nexus wherein the observed phenomena and the proposed utilities (bottom of page 3 of the previous office action). Further, it was noted that the basis of the rejection focuses on the fundamental applications as proposed by the specification, and not the potential clinical problems or applicability. Finally, it was acknowledged by the Examiner in part that a claimed invention need not teach the best method of accomplishing a particular task, and only need be useful to some extent or in accomplishing certain applications, citing *Carl Zeus Stiftung v. Renishaw*.

However, contrary to Applicants' assertion the ability of a cell to implant and differentiate does not make it a reservoir of cells in cases of a degenerative disease. First, the specification does not teach what degenerative diseases can be affected by *in utero* implantation. Moreover, it does not provide a basis for why the implanted cell would be immune to the effects of any given degenerative disorder. For example, there are several degenerative disorders

Art Unit: 1632

associated with the immune system wherein the immune system attacks antigens present on a cell such as in diabetes or MS, and it is unclear how an implanted cell will avoid the immune system in these diseases. In another example, the presence of an implanted cell does not make immune to external insults that result in a degenerative disorder such cirrhosis of the liver or affects of toxic or carcinogenic compounds. As noted in Applicants arguments the specification asserts a utility that has been thoroughly considered but demonstrated to neither substantial nor specific even in light of the working examples. Again, it is not contended that implantation of cells will not occur, rather it is maintained that practicing this method has not specific nor substantial utility because these cells do not act as reservoirs in degenerative disease cases as asserted by the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial or specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

As discussed above, the point of the rejection is not that mesenchymal cells will not implant themselves when administered *in utero*, rather that the specification fails to teach any

Art Unit: 1632

specific or substantial circumstance to practice the method as claimed to provide a “reservoir of cells” or any of the other proposed utilities, in a fetus or resulting animal.

Conclusion

No claim is allowed. The claims are free of the art of record because the art of record does not teach nor suggest implanting mesenchymal in utero. However, the claims are subject to other rejections.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Weitach whose telephone number is (571) 272-0739.

Art Unit: 1632

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571)272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number (571)272-0532.

Joseph T. Voitach

Joe Waita
AU1632